IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:		
K. Miyazawa, et al.	)	Examiner: **R. Loewe**
	)	
Serial No.: **10/534,399**	)	Group Art Unit: **1712**
	)	
Filed: **May 10, 2005**	)	Docket: **TOS-162-USA-PCT**

For: **Polysiloxane Having Phosporylcholine Group And Process For Producing The Same**

APPELLANT'S BRIEF ON APPEAL

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir: The undersigned respectfully appeals to the Patent Board of Appeal and Interferences the final rejection of the above-identified application, as stated in the Final Office Action mailed herein on January 2, 2008.

TABLE OF CONTENTS

1. REAL PARTY IN INTEREST

The real party in interest of the above-captioned patent application is the assignee, Shiseido Co., Ltd.

2. RELATED APPEALS AND INTERFERENCES

None.

3. STATUS OF THE CLAIMS

1. Cancelled
2. Rejected
3. Cancelled
4. Rejected
5. Rejected

The claims on appeal are claims 2, 4, and 5.

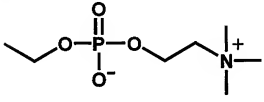
4. STATUS OF AMENDMENTS

No amendment was filed after the final rejection, and no Advisory Action was received after the final rejection.

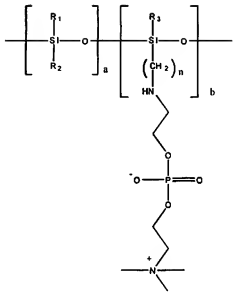
5. SUMMARY OF THE CLAIMED SUBJECT MATTER

The present invention provides a polysiloxane having a phosphorylcholine group represented by the following general formula (1).

(1)



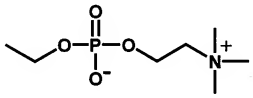
This modified polysiloxane has a wide range of application as a biocompatible material and a cosmetic material. In particular, the polysiloxane can have repeating units a and b represented by the following formula (5):



(5)

wherein R_1, R_2, and R_3, independently of each other, denote an alkyl group or perfluoroalkyl group having 1-22 carbon atoms, an alkoxysilyl group having 1-6 carbon atoms via an alkylene group having 1-6 carbon atoms, a phenyl group, or hydroxyl group, n denotes an integer 1-22; and a and b denote constituent units of the polysiloxane,

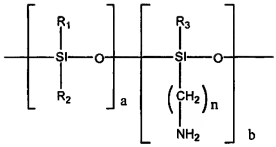
wherein said polysiloxane is obtained by introducing a phosphorylcholine group represented by the following formula (1):



(1)

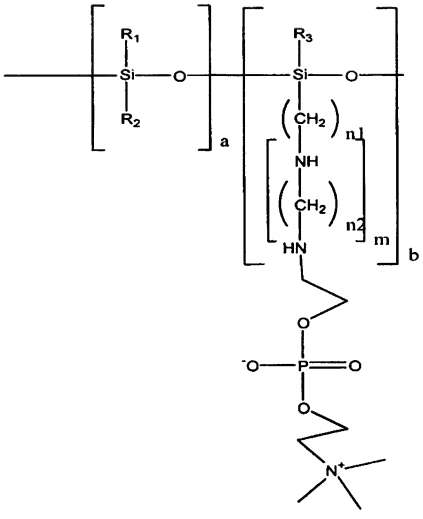
to some or all of the amino groups of the amino-modified polysiloxane having repeating units a and b represented by the following formula (2):

(2)



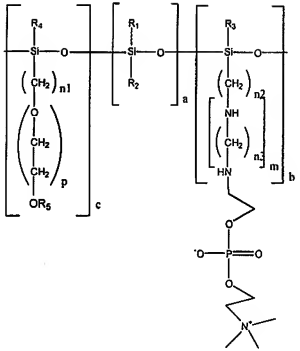
wherein R_1, R_2, and R_3, independently of each other, denote an alkyl group or perfluoroalkyl group having 1-22 carbon atoms, an alkoxysilyl group having 1-6 carbon atoms via an alkylene group having 1-6 carbon atoms, a phenyl group, or hydroxyl group, n denotes an integer 1-22, and a and b denote constituent units of the polysiloxane.

Alternatively, the polysiloxane can have repeating units a and b represented by the following formula (6):



(6)

or the polysiloxane can have repeating units a, b and c represented by the following formula (7):



(7)

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

I. Whether Claims 2, 4 and 5 comply with the written description requirement of 35 U.S.C. 112, first paragraph.

II. Whether it is necessary in the examples to define the term a, b, and/or c, in the commercially available starting materials used in these examples.

7. ARGUMENTS

The Issues

The Examiner predicates the final rejection on 35 U.S.C. 112, first paragraph, because applicants allegedly "have not defined the terms "a, b, and c" in either the specification or the claims". The Examiner further alleges that the "working examples fail to provide any conclusive data as to the numerical value of a, b, and c; determination of these values require that the commercially available starting materials KF-86, X-22-3939A, and KF-393 are defined in terms of the numerical values of a, b, and/or c". This rejection raises a number of important issues as follows:

1. Whether the specification and/or claims define the terms a, b, and c.

2. Whether the working examples provide conclusive data as to the numerical values of a, b, and c.

3. Whether applicants are entitled to be their own lexicographer in defining the terms a, b, and c.

4. Whether applicants definition of a, b, and c is sufficient to satisfy 35 U.S.C. 112, first paragraph.

5. Whether the Examiner has provided extrinsic evidence showing that applicant's definitions of a, b, and c is contrary to the customary or usual practice in the art.

Appellants respectively submit that the answer to the first four issues is in the affirmative, and that the answer to the fifth issue is in the negative for reasons set forth in the discussion below.

The Law

An applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s). See *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994). An inventor may define specific terms used to describe an invention, but must do so "with reasonable clarity, deliberateness, and precision" and, if done, must "set out his uncommon definition in some manner within the patent disclosure' so as to give one of ordinary skill in the art notice of the change" in meaning (quoting *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1387-88, 21 USPQ2d 1383, 1386 (Fed. Cir. 1992)).

Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999). A meaning of

words used in a claim is not construed in a "lexicographic vacuum, but in the context of the specification and drawings"). Any special meaning assigned to a term "must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of experience in the field of the invention." *Multiform Desiccants Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1477, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998). See also *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999) and MPEP § 2173.05(a).

The specification should also be relied on for more than just explicit lexicography or clear disavowal of claim scope to determine the meaning of a claim term when applicant acts as his or her own lexicographer; the meaning of a particular claim term may be defined by implication, that is, according to the usage of the term in >the< context in the specification. See *Phillips v. AWH Corp.*, *>415 F.3d 1303<, 75 USPQ2d 1321 (Fed. Cir. 2005) (*en banc*); and *Vitronics Corp. v. Conceptronic Inc.*, 90 F.3d 1576, 1583, 39 USPQ2d 1573, 1577 (Fed. Cir. 1996).

Consistent with the well-established axiom in patent law that a patentee or applicant is free to be his or her own lexicographer, a patentee or applicant may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings if the written description clearly redefines the terms. See, e.g., *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999), in which the court stated: "While we have held many times that a patentee can act as his own lexicographer to specifically define terms of a claim contrary to their ordinary meaning," in such a situation the written description must clearly

redefine a claim term "so as to put a reasonable competitor or one reasonably skilled in the art on notice that the patentee intended to so redefine that claim term."). *Hormone Research Foundation Inc. v. Genentech Inc.*, 904 F.2d 1558, 15 USPQ2d 1039 (Fed. Cir. 1990).

Accordingly, when there is more than one definition for a term, it is incumbent upon applicant to make clear which definition is being relied upon to claim the invention. It is appropriate to compare the meaning of terms given in technical dictionaries in order to ascertain the accepted meaning of a term in the art. *In re Barr*, 444 F.2d 588, 170 USPQ 330 (CCPA 1971). >See also MPEP §2111.01.<

The ordinary and customary meaning of a term may be evidenced by a variety of sources, >including "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art."< *Phillips v. AWH Corp.*, *>415 F.3d at 1314<, 75 USPQ2d **>at 1327.< If extrinsic reference sources, such as dictionaries, evidence more than one definition for the term, the intrinsic record must be consulted to identify which of the different possible definitions is most consistent with applicant's use of the terms. *Brookhill-Wilk 1*, 334 F. 3d at 1300, 67 USPQ2d at 1137; see also *Renishaw PLC v. Marposs Societa" per Azioni*, 158 F.3d 1243, 1250, 48 USPQ2d 1117, 1122 (Fed. Cir. 1998) where the court stated: "Where there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meanings."

If more than one extrinsic definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all consistent meanings. ** See *>e.g.,< *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001)(explaining the court's analytical process for determining the meaning of disputed claim terms); *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999).

Claims drawn to the use of known chemical compounds must have a corresponding written description only so specific as to lead one to that class of compounds. *In re Herschier.* (CCPA 1979) 591 F2d 693, 200 USPQ 711. The PTO has the burden of proving that one skilled in the art would not recognize the invention as defined in the claims from the disclosure. *In Re Voss*, (CCPA 1977) 557 F2d 812, 194 USPQ 267, or that the disclosure contains insufficient information to enable one of ordinary skill in the art to practice the invention without the necessity for undue experimentation. *Ex parte Forman, et al.* (BPAI 1986) 230 USPQ 546; *In re Angstadt*, (CCPA 1976) 537 F2d 498, 190 USPQ 214. See also concurring opinion in *In re Colanni*, (CCPA 1977) 561 F2d 220, 195 USPO 150, 162.

The structure of claimed chemical compounds as disclosed in the specification cannot be questioned on the unsupported skepticism of the Examiner. *Ex parte Linn*, (POBA 1959) 123 USPQ 262; *Ex parte Rosenwald*, (POBA 1959) 123 USPQ 261.

It is not necessary that every last detail of an invention be described, by working examiners or otherwise. *Ex parte Wolters, et al.*, (POBA 1979) 214 USPQ 735. A patent specification is not intended to be a production specification. *In re Gay*, (CCPA 1962) 309 F2d

768, 135 USPQ 311.

A specification need not disclose every operative example of a broad class of agents which are a component of a claimed composition when one skilled in the art is fully apprised by applicant's disclosure of what the invention is and how to use it. *In re Boller*, (CCPA 1964) 332 F2d 382, 141 USPQ 740. An omission from the specification of a description of some aspect of the claimed invention is not fatal where the disclosure is sufficient to enable one skilled in the art to practice the invention. The specification need not teach or disclose in detail that which is well known in the art. *In re Myers* (CCPA 1969) 410 F2d 420, 161 USPQ 668; *GeneralElectric Co. v. Brenner*, Comr. Pats. (CADC 1968) 407 F2d 1258, 159 USPQ 335.

The complete stereo configuration of a chemical compound need not necessarily be disclosed in order for the disclosure thereof to meet the requirements of 35 U.S.C. 112. *Spero v. Ingold, et al.* (CCPA 1967) 377 F2d 652, 153 USPQ 726.

When the claims are directed to a mixture of compounds of the same general formula and not to any single compound in the mixture, it is unnecessary for the specification to disclose the ring position of the radicals on each compound of the mixture when the utility of the mixture is not dependent on the position of these radicals. *In re Steinhauer, et al.* (CCPA 1969) 410 F2d 411, 161 USPQ 595.

Discussion

Respecting the first issue above, appellants respectfully submit that a, b, and c are defined two different ways in the specification on page 13, lines 8-18, as follows:

"Also, a, b, and c denote constituent units of the polysiloxane, that is, the polymer as a units, b units, and c units. Other constituent units may be contained in addition to polymers composed only of a units and b units and polymers composed only of a units, b units, and c units. Also, a units, b units, and c units may either be arranged in a random fashion or in blocks.

When a, b, and c are represented by numbers, they denote molar ratios (polymer composition) of the corresponding constituent units".

The specification on page 4, lines 16-24, also discloses that a, b, and c represent repeating units as in the formulas (2), (3), and (4) set forth on page 5 of the Specification.

Further, original claim 2, which forms part of the original disclosure, also defines a, b, and c as representing repeating units represented by formulas (2), (3), and (4) in original claim 2.

On the basis of these disclosures, there can be no doubt that the specification and original claim 2 specify that a, b, and c can be defined as representing repeating units of a polysiloxane. Thus, it is clear that the Examiner erred as to the first issue above.

Respecting the second issue, appellants respectfully urge that several working examples provide conclusive data as to the numerical values of repeating units a and b.

In Example 1 on page 20 of the specification, there is described a polysiloxane commercial product KF-86 having an average molecular weight of 50,000. The polysiloxane is shown in Fig. 4 and is described as having a ratio of a:b=50:1, and an H NMR chart for this polysiloxane is shown in Fig. 7. The specification on page 19, lines 8-12, states that:

"The composition of each constituent unit of the polysiloxane of the present invention can be determined by NMR."

Appellants respectfully urge that with this data one of ordinary skill in the polymer art, i.e., a polymer chemist with a master's and/or Phd. in polymer chemistry, could calculate the numerical value of a and b in the polysiloxane KF-86.

Further, in Example 3, applicants disclosed on page 22 that the commercial product KF-93 had an average molecular weight of 3,000, a ratio of a:b=5:1, and an H NMR chart shown in Fig. 8. It is respectfully urged that with this data one of ordinary skill in the polymer art could determine the value of a and b with the data in Example B.

Importantly, the Examiner has failed to provide any textbooks, dictionaries, or other extrinsic evidence to refute the statements in the specification on page 9, lines 8-12, that an NMR shows the composition of each constituent in the polysiloxane.

Contrary to the Examiner's assertions, Examples 1 and 3 provide conclusive evidence as to the values of a and b units in the polysiloxane.

Respecting the third issue, it is respectfully submitted that applicants are entitled to be their own lexicographer in defining a, b, and c. It is respectfully urged that the specification sections referenced above describe and define a, b, and c with reasonable clarity, deliberateness, and precision to provide one of ordinary skill in the art with applicants' intended meaning of these terms.

In view of the foregoing and the above authorities, appellants are entitled to define the terms a, b, and c in the manner set forth in the specification.

Respecting the fourth issue, the Examiner has provided no evidence that one skilled in the art would not recognize the invention defined in the disclosure as required by *In re Boss*, or that

the disclosure contains insufficient information to enable one of ordinary skill in the art to practice the invention without the necessity of undue experimentation.

The structure of the described polysiloxane as disclosed in the specification cannot be questioned on the unsupported skepticism of the Examiner. See *Ex parte Linn*, and *Ex parte Rosenwald,* above. Consequently, in the absence of any evidence to the contrary, the specification is sufficient to satisfy 35 U.S.C. 112, first paragraph, and the Examiner has erred with respect to the fourth issue.

Respecting the fifth issue, the Examiner has presented no evidence whatever showing that applicants' definition of a, b, and c are contrary to the customary or usual definition in the polymer art. Consequently, the unequivocal answer to the fifth issue is in the negative.

8. SUMMARY

Appellants traverse the final rejection based on 35 U.S.C. 112, first paragraph, on the grounds that the Examiner erred in a number of respects, and, the rejection is unfounded.

First, the specification on page 13, lines 8-18, clearly defines a, b, and c. There is additional disclosure of a, b, and c in the specification on page 4, lines 16-24, as well as in original claim 2.

Secondly, working Examples 1 and 3 provide conclusive data as to the numerical values of a and b. In particular, the average molecular weight and numerical ratio of a and b in the polysiloxane polymer is disclosed as well as NMR for that polysiloxane. It is respectfully submitted that one of ordinary skill in the art with this data would be able to determine the structure of the polymers in Examples 1 and 3.

Third, the applicants are entitled to be their own lexicographer in defining the terms a, b, and c. It is respectfully urged that the specification defines a, b, and c with reasonable clarity, deliberateness, and precision so as to provide to one skilled in the art with applicants' meaning of these terms.

Fourth, the Examiner has provided no evidence that one skilled in the art would not recognize the invention defined in the specification, or that the disclosure contains insufficient information to enable one of ordinary skill in the art to practice the invention without the necessity of undue experimentation.

Fifth, the Examiner has presented no evidence showing that applicants definitions of a, b, and c are contrary to customary or usual practice in the polymer art.

For these reasons, it is respectfully urged that the rejection is fatally flawed and entirely without merit. Consequently, the rejection should be summarily reversed.

Respectfully submitted,

TOWNSEND & BANTA

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By
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Reg. 22,069

CUSTOMER NO. 27955

Date: September 30, 2008

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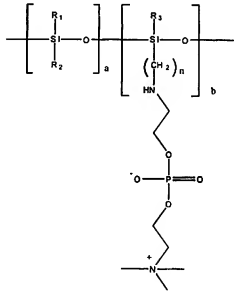
APPENDIX I (CLAIMS APPENDIX)

The Claims on Appeal

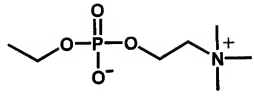
2. A polysiloxane having repeating units a and b represented by the following formula (5):



(5)

wherein R_1, R_2, and R_3, independently of each other, denote an alkyl group or perfluoroalkyl group having 1-22 carbon atoms, an alkoxysilyl group having 1-6 carbon atoms via an alkylene group having 1-6 carbon atoms, a phenyl group, or hydroxyl group, n denotes an integer 1-22; and a and b denote constituent units of the polysiloxane,

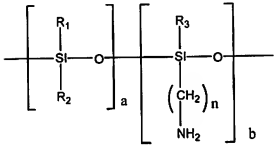
wherein said polysiloxane is obtained by introducing a phosphorylcholine group represented by the following formula (1):



(1)

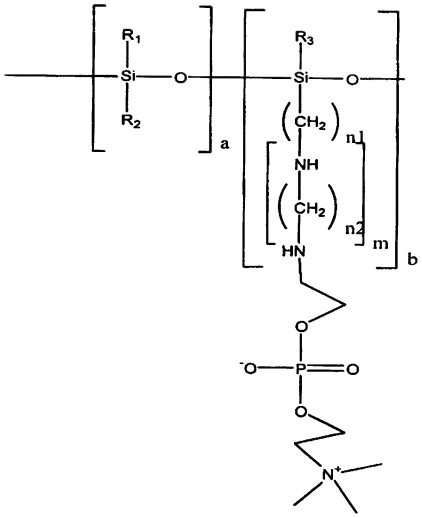
to some or all of the amino groups of the amino-modified polysiloxane having repeating units a and b represented by the following formula (2):

(2)



wherein R_1, R_2, and R_3, independently of each other, denote an alkyl group or perfluoroalkyl group having 1-22 carbon atoms, an alkoxysilyl group having 1-6 carbon atoms via an alkylene group having 1-6 carbon atoms, a phenyl group, or hydroxyl group, n denotes an integer 1-22, and a and b denote constituent units of the polysiloxane.

4. A polysiloxane having repeating units a and b represented by the following formula (6):

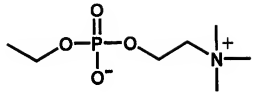


(6)

wherein R_1, R_2 and R_3, independently of each other, denote an alkyl group or perfluoroalkyl group having 1-22 carbon atoms, an alkoxysilyl group having 1-6 carbon atoms via an alkylene group having 1-6 carbon atoms, a phenyl group, or hydroxyl group; n_1 and n_2, independently of each other, denote an integer 1-22; m denotes an integer 0-10; and a and b denote constituent units of the polysiloxane, and

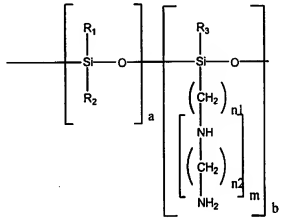
wherein said polysiloxane is obtained by introducing the phosphorylcholine group

represented by the following formula (1):



(1)

to some or all of the amino groups of the amino-modified polysiloxane having repeating units a and b represented by the following formula 3:

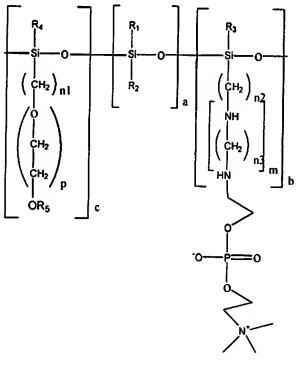


(3)

wherein R_1, R_2, and R_3, independently of each other, denote an alkyl group or perfluoroalkyl group having 1-22 carbon atoms, an alkoxysilyl group having 1-6 carbon atoms via an alkylene

group having 1-6 carbon atoms, a phenyl group, or hydroxyl group; n_1 and n_2, independently to each other, denote an integer 1-22, m denotes an integer 0-10; and a and b denote constituent units of the polysiloxane.

5. A polysiloxane having repeating units a, b and c represented by the following formula (7):

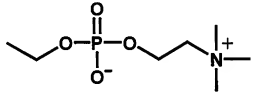


(7)

wherein R_1, R_2, R_3, and R_4 independently of each other, denote an alkyl group or perfluoroalkyl group having 1-22 carbon atoms, an alkoxysilyl group having 1-6 carbon atoms via an alkylene group having 1-6 carbon atoms, a phenyl group, or hydroxyl group; R_5 denotes a hydrogen atom or an alkyl group having 1-22 carbon atoms; n denotes an integer 1-22; n_1, n_2, and

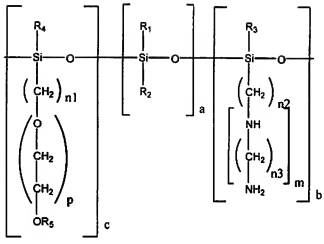
n_3, independently of each other, denote an integer 1-22; m denotes an integer 0-10; p denotes an integer 1-30; and a, b and c denote constituent units of the polysiloxane, and

wherein said polysiloxane is obtained by introducing the phosphorylcholine group represented by the following formula (1):



(1)

to some or all of the amino groups of the amino-modified polysiloxane having repeating units a and b represented by the following formula 4:



(4)

wherein R_1, R_2, R_3 and R_4, independently of each other, denote an alkyl group or perfluoroalkyl group having 1-22 carbon atoms, an alkoxysilyl group having 1-6 carbon atoms via an alkylene group having 1-6 carbon atoms, a phenyl group, or hydroxyl group; n_1, n_2, and n_3, independently to each other, denote an integer 1-22; m denotes an integer 0-10, p denotes an integer 1-30, and a, b, and c denote constituent units of the polysiloxane.

APPENDIX II (EVIDENCE APPENDIX)

Evidence

None.

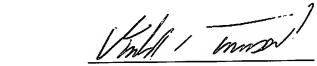
APPENDIX III

Related Proceedings

None.

CERTIFICATE OF TRANSMISSION

I hereby certify that this facsimile transmission, consisting of a 22-page Appellant's Brief on Appeal, as well as Appendices I-III, in Docket No. TOS-162-USA-PCT, Serial No. 10/534,399, filed May 10, 2005, is being electronically transmitted to the U.S. Patent and Trademark Office on September 30, 2008.



Donald E. Townsend